

# Seeking Authorisation to Conduct Non-Research Projects within the Trust

The Ethics Sub-Committee acts as an advisory group for the Trust Board and Clinical and Research and Development Directors. It has been set up to advise the directorates on matters concerning both clinical ethical issues and non-research projects such as audit, focus groups, evaluation, surveys etc when they directly involve service users and/or their carers or Trust staff.

The Ethics Sub-Committee will provide scrutiny and overview of all non-research projects in the Trust, which fall outside standard clinical care and involve service users and/or carers in order to ensure that such projects fulfil ethical criteria.

**Any non-research project requires approval by the relevant Clinical Director before participants are recruited and/or data is collected. The Clinical Director's decision will be informed by the advice of the ELCMHT Ethics Sub-Committee. All applicants apply to the relevant Clinical Director and the Trust Ethics Sub-Committee simultaneously through the use of the Ethics Approval Form.**

The Ethical Approval Form has been developed to facilitate a fast screening service for project consideration; the form and these guidance notes are available on the P: Drive Clinical Governance folder / Ethics Subcommittee folder / Project Registration folder / Ethical Approval Form.

## What is A Non-Research Project?

The difference between clinical audit and other non-research activity and research is not always clear and there will be some grey areas where specialist advice is needed.

**Some guidance is given below, which might help you make decisions regarding where to seek ethical approval.**

Research	Audit	Service Evaluation
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.

### **Seeking Authorisation to Conduct Non-Research Projects, cont.**

Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: “Does this service reach a predetermined standard?”	Designed to answer the question: “What standard does this service achieve?”
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research -may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups.	No allocation to intervention groups: the health care professional and patient have chosen intervention.	No allocation to intervention groups: the health care professional and patient have chosen intervention.
Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	before clinical audit.	before service evaluation.
May involve randomisation	No randomisation	No randomisation
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:		
RESEARCH REQUIRES REC REVIEW	AUDIT REQUIRES TRUST REVIEW	SERVICE EVALUATION REQUIRES TRUST REVIEW

If the answer is yes to any of the following questions then the project should be submitted to a Research Ethics Committee:

- Does the project involve procedures outside the normal treatment processes? (e.g. targeted groups of service users identified by diagnosis or research-based selection criteria)

### **Seeking Authorisation to Conduct Non-Research Projects, cont.**

- Does the survey relate to a contentious area? (e.g. views of euthanasia, etc)
- Is the project a case note study, which includes the health records of patients who have been discharged to other providers?

If you feel that your project is non-research, the following procedures will apply:

- 1) Your project will require approval from the relevant Clinical Director.
- 2) To obtain this approval:
  - a) All clinical audits will continue to be registered under the current Clinical Audit process.<sup>1</sup> There is an Ethics questionnaire to be completed within the Audit registration form and, if there are ethical issues, this screening process automatically generates referral to the Trust Ethics Sub-Committee.
  - b) All other non-research projects will be submitted using the Ethical Approval Form.
- 3) Odud Miah will acknowledge receipt of the form by email and confirm the date on which the proposal will be discussed at the Trust Ethics Sub-Committee.
- 4) All projects screened by the Ethics Sub-Committee are entered on the Trust Audit Database under a separate field.
- 5) The Trust Ethics Sub-Committee will meet monthly to consider all submissions and advise the relevant Clinical Director about any ethical issues, which require attention prior to approval being granted.
- 6) If the Trust Ethics Sub-Committee is in doubt about whether a project submitted constitutes “research”, it will consider advising referral to the LREC.
- 7) The Clinical Director will inform the applicant of the outcome of the process.

If you feel that your project is research, please contact the Research and Development Office in the Academic Unit on 020 7540 6755.

### **Guidance on Completing the Trust Ethical Approval Form**

The Trust's Ethical Approval Form is an MSOutlook form with several tabs listed across the top of the page. Please ensure that you complete **all** sections in each of the tabs (*except* the tab marked 'Ethics Committee Only') before submitting your project. The Ethics Subcommittee will **not** accept any other format, other than the Ethical Approval form.

***Please remember that you must receive authorisation from the Clinical Director BEFORE you recruit any participants and/or collect any data.***

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<sup>1</sup> Further information about clinical audit can be found on the P: Drive – Clinical Governance folder – Clinical Audit folder

## **Seeking Authorisation to Conduct Non-Research Projects, cont.**

### Tab 1: Ethical Approval Form

- The name 'Odud Miah' should appear automatically in the 'To:' address box; if it does not, please ensure that it is added.
- The name 'Cathie O'Driscoll' should appear automatically in the 'CC:' address box; if it does not, please ensure that it is added.
- Please add the e-mail address of the appropriate Clinical Director by clicking on the 'CC:' box. A list of current clinical directors are provided below:

<b>Older Adults by locality</b>	<b>General Adults by locality</b>	<b>Trust Wide</b>
City & Hackney – Gerry O'Mahony	City & Hackney – Trevor Turner	CAMHS – Liz Walters
Newham – Gabrielle Faire	Newham – Frank Rohricht	Addictions – Vanessa Crawford
Tower Hamlets – Peter Bell	Tower Hamlets – Prof. Dave Curtis	Forensics – Neil Boast

- When the form is fully completed, submit it by clicking on the 'Sent' button in the upper left-hand corner of the page. A copy of the form is automatically saved to your 'Sent Items' folder, which is accessible via the Outlook menu.

### Tab 2: Project Details

#### Section 1: Your Details

- This should be the details of the project lead / lead clinician, even if a different person is actually filling in the form.
- Please enter the name, job title, contact mailing address and e-mail address, and contact telephone number in the appropriate boxes.

#### Section 2: Project Details

- Using the drop-down arrow (located on the right-hand side of the response box), please select the locality, directorate/service area and site type **where the participants will be recruited from and / or where the data to be collected is to be found**. This may be different from the place where you normally work and from where you will analyse the information.
- Please then specify in the free-text box all the teams/wards that will be involved in the project, including those from where you will recruit participants and / or collect data even if they are not part of the project team.
- The question 'Are staff from more than one discipline involved in the development of this project?' should be answered 'yes' or 'no' using the drop-down arrow. This refers only to the team developing/designing the project – and not to potential participants. Please then list the name and profession (e.g., occupational therapist, nurse, psychiatrist, etc.) of all people in addition to the project lead named in section one, who make up the project team.
- Use the drop-down arrow to select 'yes' or 'no' in answer to the question 'Are service users involved in the development of this project?' The Department of Health

### ***Seeking Authorisation to Conduct Non-Research Projects, cont.***

encourages the involvement of service users in all aspects of service evaluation and development. If you have or plan to include service users in the project design, please describe their involvement in the free text box

#### Section 3: Project proposal

- Type the name of the project in the first free-text field
- Insert an electronic copy of your project protocol in the following field. Please do not attempt to re-type or copy out all the text in your protocol, instead, just send the file in a separate email to Odud Miah.
- Start date: enter the date on which you propose to begin recruitment and/or data collection
- End date: enter the date on which you expect the project to be complete and the results available/published.
- List the source of all data for the project – e.g., case notes, responses to questionnaires, transcripts of interviews and/or focus groups, specific Trust IT systems, etc.

#### **Writing a Project Protocol**

The following advice is intended for those with little or no experience in writing proposals.

Before you start to write your proposal there are some key points to consider:

What you want to do?

What will be the value of doing it?

How much it will cost (in terms of hard cash, resources, personnel, equipment etc)?

How long it will take?

What difference will the project make to the NHS/patient care?

What has already been done in this project area?

How will you plan to do it?

How will you evaluate the results?

How will you disseminate the results?

#### **Components of a Proposal**

1. Title: The title of the project needs to strike a balance between being explicit but to the point, whilst being comprehensive enough to explain the nature of the project and its objectives.

### ***Seeking Authorisation to Conduct Non-Research Projects, cont.***

2. Abstract: This essentially gives the reader an outline of the project, highlighting its main points. Although the abstract appears first it should be written last as a concise summary of the project and should, in general, be no more than 200 words in length. The major objectives and procedures should be mentioned in this section: project design, method and an outline of the expected findings.
3. Introduction: The introduction should familiarise the reader with the subject matter and give a general idea of the proposed project. It should also establish how important the results of the project would be in terms of clinical practice, policy or the NHS as a whole.
  - 3.1. Background: If the project is relatively simple this section can be incorporated in the introduction, however for more complex studies a separate subsection of the introduction, entitled 'background' is useful. This subsection should incorporate a review of the literature and should identify the extent and quality of work that has already been carried out in the topic area. It should also explain why further work in this area is necessary and how it will build upon previous knowledge.
  - 3.2. Aims and objectives: The general aims of the project should be clearly stated in this subsection and the objectives listed, including any benefits the project may have and how the results will be applied.
4. Method: This section deals with project design and should include:
  - i. Number of subjects to be studied
  - ii. Sampling methods – how the participants will be selected, including reasons for inclusion/exclusion of participants.
  - iii. Recruitment strategy
  - iv. Project design
  - v. Method of data collection
  - vi. Method of data analysis
5. Benefits of the project: The benefits of the project need to be identified especially in terms of clinical impact and benefits to patients and the Trust. Benefits can also be determined in terms of cost, knowledge or identifying areas for further investigation.
6. Resources and costs: All the potential costs should be listed here:
  - i. Infrastructure costs – space, time etc.
  - ii. Project Costs – equipment, personnel
  - iii. Service support costs – additional patient care costs e.g., x-rays, imaging, nursing time
  - iv. Excess treatment costs – where patient care costs are in excess of standard treatment costs

## **Seeking Authorisation to Conduct Non-Research Projects, cont.**

*These categories have been defined by Health Service guidelines (97)32*

7. Project plan/milestones: A timetable for the project should be produced listing all activities that need to be carried out and milestones to be achieved should be listed here as well.
8. References: A list of all references used should be produced in the order that they were referred to in the proposal.

When you have finished you should make sure that the following questions have been answered in the proposal and that ethical considerations have been addressed.

Have you explained the purpose of the project – aims/objectives?

Have you described the project design adequately?

Have you identified the participants clearly?

Have you clearly defined what information will be collected?

Have you considered how the data will be analysed?

### Section 4: Sign off

Please answer yes or no using the drop-down arrow whether your line manager has agreed the project.

If yes, please attach an email from the project lead's line manager expressing his/her agreement.

### Tab 3: DPA/Confidentiality

Please select all answers from the drop down menus.

### Tab 4: Ethics

In each section, please describe any ethical issues that arise from this project and how you propose to mitigate these concerns. The following issues may be pertinent to your proposal:

#### Section 1: Risks/Benefits

Any proposal needs to weigh up the possible risks to participants against the potential benefit to the service of the work. Please keep in mind the following questions when completing this section:

- If any intervention or procedure, which would normally be considered a part of routine care, be withheld from the project participants – if so, please justify
- Will project participants will receive any clinical intervention(s) or procedure(s) over and above those that would normally be considered a part of routine clinical care.

### **Seeking Authorisation to Conduct Non-Research Projects, cont.**

- Will project participants will receive any non-clinical intervention(s) or procedure(s). *(These include interviews, non-clinical observations and use of questionnaires.)*
- Will individual or group interviews/questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could take place during the study (e.g. during interviews/group discussions, or use of screening tests for drugs)? *If yes, give details of procedures in place to deal with these issues. The Participant Information Sheet should make it clear under what circumstances action may be taken.*
- What is the potential for pain, discomfort, distress, inconvenience or changes to lifestyle for project participants?
- What is the potential for benefit to project participants?
- What is the potential for adverse effects, risks or hazards, pain, discomfort, distress, or inconvenience to those conducting the study themselves? *(if any)*

### Section 2: Identification & Recruitment

When identifying potential participants and recruiting them to the study, it is important to ensure that their confidentiality and well-being are maintained. Please keep in mind the following questions when completing this section:

- How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?
- What are the principal inclusion / exclusion criteria?
- Will the participants be from any of the following groups? If so, please justify their inclusion
  - Children under 16
  - Adults with learning disabilities
  - Adults with mental illness (particularly if detained under Mental Health Legislation)
  - Adults with dementia
  - Prisoners
  - Young Offenders
  - Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students
  - Other vulnerable groups
- Is your project likely to produce real and direct benefit to the participant? If yes, please indicate the nature of this benefit. If no, please explain how your study will contribute to the greater understanding of the incapacity and to the attainment of real and direct benefit to the adult or other persons having the same incapacity:

### Section 3: Consent

In many cases, it will be necessary to obtain the consent of participants before obtaining any information about or from them for the purpose of the project. Please see the Trust's

**[Seeking Authorisation to Conduct Non-Research Projects, cont.](#)**  
[Records Management Policy](#) and [Information and IM&T Security Policy](#), which outline how personal data must be processed to comply with the DPA. You should familiarise yourself with both policies before completing this section of form.

- Will informed consent be obtained from the participants? If yes, give details of who will take consent and how it will be done. If consent is not to be obtained, please explain why not.

Where it is necessary to obtain consent, you must take particular care to ensure that anyone you ask to consider taking part in the project is given the fullest possible information, presented in terms and a form that they can understand. This must include any information about possible benefits and risks; and advice that they can withdraw at any time. You must not put pressure on anyone to take part in the work. You must obtain the person's consent in writing.

You should seek further advice where your project will involve adults who are not able to make decisions for themselves, or children. You should be aware that in these cases the legal position is complex or unclear, and there is currently no general consensus on how to balance the possible risks or benefits to such vulnerable individuals against the public interest. You should consult the guidance issued by bodies such as the [Medical Research Council](#) and the medical royal colleges to keep up to date.

If your project involves minors and adults who are unable to consent for themselves, a legal representative may give their *assent* on behalf of the patient. You should write separate information sheets and consent forms for a legal representative to read and sign. These should contain the same information as a normal information sheet and consent form, but should be written from the perspective of the legal representative. COREC offers some [guidance](#) on the role and responsibilities of a legal representative.

- If participants are to be recruited from any of the potentially vulnerable groups listed in section 2, give details of extra steps taken to assure their protection. Describe any arrangements to be made for obtaining consent from a legal representative.

For consent to be legally valid, the participant must be both competent and legally entitled to consent. It is strongly recommended that consent should be obtained in writing. If it is not, however, this should be fully justified on the ethics form, and the verbal consent must be fully documented and witnessed. You must ensure that on your written consent form you have considered specific clauses for the following:

- Consent to participate in the study
- Consent to process data from the study
- Permission to inform GPs of their patients' participation
- Arrangements for ensuring confidentiality of participant's personal information
- If videoing/photography is involved in project – must have specific clause seeking consent for this

The COREC guidelines on writing the [Patient Information Sheet and Consent form](#) offer excellent advice and provide a template format for both documents. We recommend that you make use of these templates and adapt them to the specific contents of your project.

- Copies of the written information and all other explanatory material should accompany this application.

## **Seeking Authorisation to Conduct Non-Research Projects, cont.**

### **Rights of Participants**

Anyone that you hold information on has a right under the Act to access any personal data that you hold about him or her. You must give them access within 40 days of their request. The participant also has a right to request that you stop processing their data. If you receive such a request, you must comply, even if it means removing that person from the project. The easiest way of meeting the requirements of the Data Protection Act is to be as open and honest as possible with the data subject regarding how the data you collect will be used, and who will have access to this data. Participants must know that any information kept on them because of their involvement with the project will be kept securely.

#### Section 4: Payment / Conflict of interest

Payment for participation and other situations may create a conflict of interest in the work, which might raise an ethical concern. Please keep in mind the following questions when completing this section:

- Will individual project participants receive any payments for taking part in this project? If yes, indicate how much and on what basis this has been decided:
- Will individual project participants receive reimbursement of expenses or any other incentives or benefits for taking part in this project? If yes, indicate how much and on what basis this has been decided:
- Will individual project team members receive any personal payment over and above normal salary for undertaking this project? If yes, indicate how much and on what basis this has been decided:
- Will individual project team members receive any other benefits or incentives for taking part in this project? If yes, indicate how much and on what basis this has been decided:
- Does the project lead or any other collaborator have any direct personal involvement (e.g. financial, share-holding, personal relationship etc.) in the organisation sponsoring or funding the work that may give rise to a possible conflict of interest?

#### Further information

We are happy to answer questions/give advice on any aspect of completing this form or requesting a consultation with the ELCMHT Ethics Sub-Committee.

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